Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)

CHAPTER XIII

SUPERVISION BY MEMBER STATES, UNION INSPECTIONS AND CONTROLS

Article 77

Corrective measures to be taken by Member States

1 Where a Member State concerned has justified grounds for considering that the requirements set out in this Regulation are no longer met, it may take the following measures on its territory:

a revoke the authorisation of a clinical trial;

b suspend a clinical trial;

c require the sponsor to modify any aspect of the clinical trial.

2 Before the Member State concerned takes any of the measures referred to in paragraph 1 it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion shall be delivered within seven days.

3 The Member State concerned shall immediately after taking a measure referred to in paragraph 1 inform all Member States concerned through the EU portal.

4 Each Member State concerned may consult the other Member States concerned before taking any of the measures referred to in paragraph 1.

Article 78

Member State inspections

1 Member States shall appoint inspectors to perform inspections in order to supervise compliance with this Regulation. They shall ensure that those inspectors are adequately qualified and trained.

2 Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.

3 Where a Member State concerned intends to carry out an inspection on its territory or in a third country with regard to one or several clinical trials which are conducted in more than one Member State concerned, it shall notify its intention to the other Member States concerned, the Commission and the Agency, through the EU portal, and shall inform them of its findings after the inspection.

4 Inspections fees, if any, may be waived for non-commercial sponsors.

5 In order to efficiently use the resources available and to avoid duplications, the Agency shall coordinate the cooperation between Member States concerned on inspections conducted in

Member States, in third countries, and inspections conducted in the framework of an application for a marketing authorisation under Regulation (EC) No 726/2004.

6 Following an inspection, the Member State under whose responsibility the inspection has been conducted shall draw up an inspection report. That Member State shall make the inspection report available to the inspected entity and the sponsor of the relevant clinical trial and shall submit the inspection report through the EU portal.

7 The Commission shall specify, by means of implementing acts, the detailed arrangements for the inspection procedures including the qualification and training requirements for inspectors. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2).

Article 79

Union controls

1 The Commission may conduct controls in order to verify:

a whether Member States correctly supervise compliance with this Regulation;

b whether the regulatory system applicable to clinical trials conducted outside the Union ensures that point 8 of the Introduction and general principles contained in Annex I to Directive 2001/83/EC is complied with;

c whether the regulatory system applicable to clinical trials conducted outside the Union ensures that Article 25(5) of this Regulation is complied with.

2 The Union controls referred to in point (a) of paragraph 1 shall be organised in cooperation with the Member States concerned.

The Commission shall prepare in cooperation with the Member States a programme for the Union controls referred to in points (b) and (c) of paragraph 1.

The Commission shall report on the findings of each Union control carried out. Those reports shall, if appropriate, contain recommendations. The Commission shall submit those reports through the EU portal.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, CHAPTER XIII.